PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00, 39/24

A1

(11) International Publication Number: **WO 98/28034**

(43) International Publication Date: 2 July 1998 (02.07.98)

(21) International Application Number: PCT/IL97/00408

(22) International Filing Date: 14 December 1997 (14.12.97)

(30) Priority Data:
119899 24 December 1996 (24.12.96) IL

(71) Applicant *(for all designated States except US)*: MEDICARD, LTD. [IL/IL]; P.O. Box 250, 20692 Upper Yoqneam (IL).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: ROTTENBERG, Dan [IL/IL]; Einstein Street 117, 34601 Haifa (IL). HAIMOVICH, Dudu [IL/IL]; Chalamit Street 12/2, 30095 Ramat Ishai (IL).

(74) Agent: FENSTER, Paul; Fenster & Company, Patent Attorneys, P.O. Box 2741, 49127 Petach Tikva (IL).

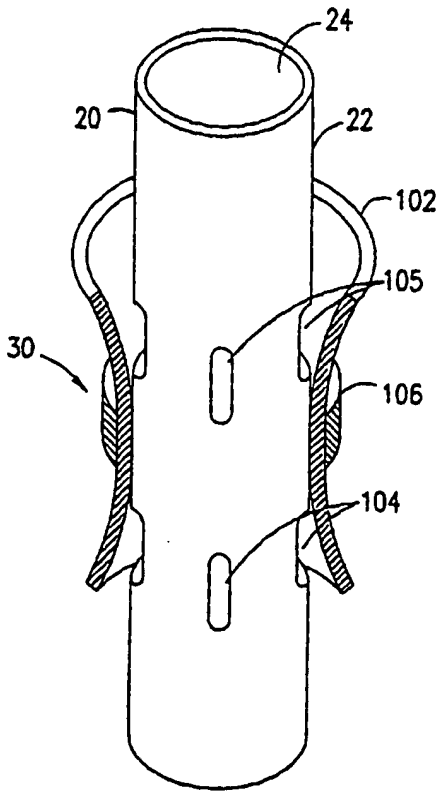
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: VALVE FOR A HEART ASSIST DEVICE

(57) Abstract

A one-way valve for use in a medical pump system, said valve comprising: an outer sheath, defining and enclosing a lumen therein, and comprising one or more radial opening; and an elastic outer sleeve, which adheres to an outer, radial surface of the sheath to cover the radial openings, closing the valve, wherein in response to an increase of a fluid pressure inside the lumen, the outer sleeve stretches outward, exposing the radial openings, so that fluid flows out of the valve in a direction determined by the sleeve, and wherein the valve is adapted to control the direction of flow.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

VALVE FOR A HEART ASSIST DEVICE

FIELD OF THE INVENTION

The present invention relates generally to devices and systems for augmenting cardiac output, and specifically to valves for use in intra-ventricular cardiac assist pumps.

BACKGROUND OF THE INVENTION

Intra-aortic and intra-ventricular cardiac assist devices are well known in the art. These devices are generally used to reduce the heart's work load after insult or surgery. They may also be used to increase blood flow from the left ventricle of the heart into the aorta in cases of insufficient cardiac output due, for example, to acute or chronic heart ailments or to interference with normal cardiac function during surgery.

One of the best-known and most widely-used intra-aortic pump systems is the Intra-Aortic Balloon Pump (IABP), comprising a catheter, having an inflatable balloon at its distal end, which is inserted through an artery into the aorta. The balloon is then alternately inflated and deflated by an external pump drive, so as to alternately block and unblock blood flow through the aorta, in synchrony with the beating of the heart, in order to assist the left ventricle in propelling blood into the arterial system. The IABP, however, provides only limited augmentation of the heart's natural, unassisted output, and is not adequate for overcoming heart failure.

U.S. patent 4,014,317, which is incorporated herein by reference, describes a cardiocirculatory assist cannula with a balloon pump and cardiac pacing electrode. The cannula is inserted percutaneously through the aorta so that its distal end is inside the left ventricle of the heart. During systole, inlet valves on the cannula inside the left ventricle open, and the contraction of the ventricle forces blood to flow into the cannula. Then, during diastole, the blood flows out, into the aorta, through one or more outlet valves along the cannula downstream from the inlet valve. A gas-filled balloon, similar in function to the IABP described above, is connected to the cannula downstream of the outlet valves. The balloon is typically inflated during diastole and deflated during systole, to assist in perfusion of the coronary arteries. The cannula has a small stroke volume, however, and relies on the contractile force of the heart to pump the blood. It is therefore of limited usefulness in augmenting the blood output of a weakened or failing heart.

U.S. patent 4,906,229, which is also incorporated herein by reference, describes a high-frequency transvalvular axisymmetric blood pump. The pump includes a small internal

volume, which may be alternately expanded and reduced by pneumatic or hydraulic pressure, which is exerted via a flexible membrane radially surrounding the volume. The volume has intake and outlet ends, with one-way axial valves at both of the ends, so that blood can flow only from the heart into the aorta. The pump is connected via the one-way intake valve to a cannula, which is inserted into the left ventricle of the heart through the aortic valve. When the internal volume is expanded, blood flows into the pump from the ventricle. The volume is then reduced, and the blood is ejected into the aorta through the outlet end. This pump is designed to operate at a frequency of 600 to 1,000 cycles per minute. Since the stroke volume of the pump is typically only about 3-5 cc, these high cycle rates are needed in order to provide adequate perfusion.

In the Hemopump Cardiac Assist System, distributed by Johnson & Johnson Interventional Systems, a cannula containing a special, miniature rotor pump mechanism is inserted into the aorta. The pump is driven by a drive unit outside the body, to pump blood continuously from the aorta into the rest of the arterial system, thereby supplementing the heart's natural output rate. A system of this type is similarly described in U.S. patent 5,092,844, which is incorporated herein by reference. While continuous-flow devices are useful for short-term augmentation of cardiac output, however, it is medically known that pulsatile pumps provide more effective long-term support, since they approximate more closely the natural pump action of the heart.

U. K. patent 1,370,546, which is incorporated herein by reference , describes heart assist apparatus that includes a pump for cardiovascular pumping of the blood and, communicating with the pump, a catheter, which is inserted into ventricle of the heart. The catheter includes an inlet valve for drawing blood from into the catheter from the left ventricle and an outlet valve for discharging the blood into the aortic arch. The outlet valve consists of slotted openings in the catheter, closed by elastic tongues on the outside of the catheter. Overpressure within the catheter, generated by the action of the pump, causes the elastic tongues to open outward, so that the blood is discharged through the openings.

U. S. Patent 3,995,617, which is also incorporated herein by reference, describes a method and device for augmenting the action of the heart. A catheter, whose proximal end is connected to a reciprocating pump, is inserted through the aortic valve into the left ventricle of the heart. During systole, the pump creates suction so that blood is drawn into the catheter through an inlet valve at the distal end of the catheter, which is positioned in the left ventricle.

During diastole, the pump pressure is increased, and blood is expelled through a plurality of outlet valves into the aorta. The outlet valves consist of a multiplicity of openings along the side wall of the catheter, covered by externally located rubber or flexible plastic cylinders or boots. The outward pressure generated in the catheter by the pump causes the cylinders or boots to expand outward, so that the outlet valves open.

The above cardiac assist devices generally make no provision for controlling or adjusting the direction of blood flow from the pump into the arterial system. The valves associated with the pumps are capable of directing blood flow out of the pumps only in a fixed, generally downstream, direction.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an adjustable, one-way valve, particularly for use in medical pump systems and cannulae.

In some aspects of the present invention, the one-way valve serves as an outlet valve of a cannula associated with a cardiac assist pump system. The valve is constructed or adjusted to control the direction of blood flow out of the cannula.

As described in PCT publication WO 97/02850, which is incorporated herein by reference, in some preferred embodiments of the present invention, an intraventricular cardiac assist pump comprises a cannula, whose distal end is inserted through the aorta into the left ventricle, and a pulsatile drive unit, coupled to the cannula at the proximal end thereof. The cannula comprises an outer sheath, defining and enclosing an internal lumen, having at least one intake valve, adjacent to the cannula's distal end, and one or more outlet valves, disposed radially along the length of the cannula, downstream from the intake valve. The pulsatile drive unit alternately reduces and increases the fluid pressure in the cannula. When the pressure is reduced, the at least one intake valve opens, while the one or more outlet valves are closed, and blood flows through the intake valve into the lumen of the cannula. The pressure in the cannula is then increased, causing the intake valve to close and the outlet valves to open, so that blood flows out of the lumen into the aorta.

Preferably, the drive is synchronized with the heart beat, so as to draw blood into the lumen of the cannula during systole and eject the blood into the aorta during diastole.

Alternatively, the drive may be counter-synchronized, so as to draw blood into the lumen during diastole and eject it during systole, or the drive may be operated asynchronously, independent of the heart beat.

In preferred embodiments of the present invention, the cannula comprises a flexible, resilient tube having a diameter in the range of 15-30 French (5-10 mm). It is preferably inserted percutaneously through the femoral artery, into the aorta, and then through the aortic valve into the left ventricle of the heart. Alternatively, the cannula may be inserted elsewhere into the arterial or venous system through a suitable surgical incision.

The at least one intake valve of the cannula may comprise a mechanical flap, leaflet or other valve type known in the art or described in the above-mentioned PCT patent application.

The outlet valves of the cannula comprise radial openings along the length thereof, which are covered and closed by a flexible, elastic outer sheath, preferably made of biocompatible rubber. The sheath is preferably held in place by a clamp, for example, a squeeze ring, along a portion of its length. Alternatively, the sheath may be glued or otherwise fastened in place.

Normally, the elasticity of the outer sheath covering the outlet valves causes it to adhere radially to the outer surface of the cannula, thereby closing the outlet valves. When the pressure inside the lumen of the cannula is increased, however, the pressure of the blood exerts an outward force on the sheath through the radial openings. This force causes the sheath to stretch outwards, allowing the blood to flow out of the lumen.

By adjusting the position of the squeeze ring, the direction of blood flow out of the outlet valves may be adjusted. In some preferred embodiments of the present invention, the squeeze ring is positioned at or near the upstream end of the sheath. Thus, the downstream end of the sheath stretches outward when the pressure inside the lumen is increased, thus directing the blood flow out of the cannula in a generally downstream direction. In other preferred embodiments of the present invention, the squeeze ring is at or near the downstream end of the sheath, so that the upstream end thereof stretches outward when the pressure is increased, and blood flow is directed in a generally upstream direction. Alternatively or additionally, either the upstream or the downstream end of the sheath may be thickened and/or stiffened, so that the other, more flexible end of the sheath will stretch outward preferentially when the pressure in the lumen is increased.

Furthermore, in still other preferred embodiments of the present invention, the squeeze ring is positioned in a predetermined location intermediate the upstream and downstream ends of the sheath. The location is chosen so as to direct the blood flow in a desired proportion between the upstream and downstream directions. Additionally or alternatively, the sizes,

number and/or positions of the radial openings in the cannula may be chosen so as to produce the desired upstream/downstream proportion, in cooperation with the sheath.

In some preferred embodiments of the present invention, the pump, cannula and outlet valve structure described above are used to enhance circulation in the coronary arteries, for example, in a subject at risk for infarction. The cannula, having its outlet valve structure adjusted to provide outflow in the upstream direction, is inserted into the aorta of a subject. Preferably, the pump drive operates in a counter-synchronized mode, so that blood is pumped out of the cannula into the aorta during diastole. Under these conditions, the blood flowing out of the outlet valve will flow preferentially into the coronary arteries. Other types of pumps, known in the art, may similarly be used for this purpose.

Although preferred embodiments are described herein with reference to a cardiac assist pump system, it will be appreciated that valves in accordance with the principles of the present invention may be used in other types of medical fluid flow devices, as well.

There is therefore provided, in accordance with a preferred embodiment of the invention, one-way valve for use in a medical pump system, said valve comprising:

an outer sheath, defining and enclosing a lumen therein, and comprising one or more radial openings; and

an elastic outer sleeve, which adheres to an outer, radial surface of the sheath to cover the radial openings, closing the valve,

wherein in response to an increase of a fluid pressure inside the lumen, the outer sleeve stretches outward, exposing the radial openings, so that fluid flows out of the valve in a direction determined by the sleeve, and

wherein the valve is adapted to control the direction of flow.

Preferably, wherein the one or more radial openings comprise at least a first opening, adjacent a proximal axial end of the sleeve, and a second opening, adjacent a distal axial end of the sleeve, such that when the sleeve stretches outward, fluid exiting the first opening flows out of the valve in the proximal direction, and fluid exiting the second opening flows out of the valve in the distal direction, in a desired proportion of proximal to distal flow.

Preferably, wherein the first and second openings are of different sizes, such that the proportion of fluid flowing out of the valve in the proximal direction to that flowing out in the distal direction is determined by the relative sizes of the first and second openings.

In a preferred embodiment of the invention, the valve comprises a retaining ring, circumferentially engaging a portion of the sleeve so as to hold the sleeve in place relative to the sheath, wherein the axial position of the retaining ring along the sleeve is adjustable so as to control the flow of fluid out of the valve.

There is further provided, in accordance with a preferred embodiment of the invention, a one-way valve for use in a medical pump system, said valve comprising:

an outer sheath, defining and enclosing a lumen therein, and comprising one or more radial openings; and

an elastic outer sleeve, which adheres to an outer, radial surface of the sheath to cover the radial openings, closing the valve,

wherein in response to an increase of a fluid pressure inside the lumen, the outer sleeve stretches outward, exposing the radial openings, so that fluid flows out of the valve in a direction determined by the sleeve,

wherein the one or more radial openings comprise at least a first opening, adjacent a proximal axial end of the sleeve, and a second opening, adjacent a distal axial end of the sleeve, such that when the sleeve stretches outward, fluid exiting the first opening flows out of the valve in the proximal direction, and fluid exiting the second opening flows out of the valve in the distal direction, in a desired proportion of proximal to distal flow, and

wherein the first and second openings are of different sizes, such that the proportion of fluid flowing out of the valve in the proximal direction to that flowing out in the distal direction is determined by the relative sizes of the first and second openings.

There is further provided, in accordance with a preferred embodiment of the invention, a cannula pump comprising:

a cannula comprising having an inner lumen formed therein;

an inlet valve communicating with the lumen; and

an outlet valve as provided above communicating with the lumen.

There is further provided in accordance with a preferred embodiment of the invention a method for controlling fluid flow out of a cannula, comprising:

opening one or more radial openings in an outer sheath of the cannula, communicating with a lumen thereof;

fitting a flexible outer sleeve over the cannula, so as to cover the one or more radial openings, wherein the sleeve stretches outward, exposing the openings, responsive to an increase in fluid pressure in the lumen;

determining a desired direction of fluid flow out of the lumen; and

fixing the sleeve to the sheath in a position such that the sleeve directs the fluid flow out of the lumen in the desired direction.

Preferably, opening the one or more radial openings comprises opening at least two openings of different sizes, responsive to the desired direction of fluid flow.

Preferably, fixing the sleeve to the sheath comprises altering the position at which the sleeve is fixed to the sheath so as to adjust the direction of fluid flow.

There is further provided, in accordance with a preferred embodiment of the invention, a method for injecting fluid into a vessel having a flow of liquid generally in a normal flow direction, comprising:

connecting a cannula, having distal and proximal ends and having an intake and a directional outlet valve, to a pump drive at the proximal end of the cannula;

inserting the distal end of the cannula into the vessel;

filling the cannula with the fluid; and

ejecting the fluid through the outlet valve of the cannula into the vessel in a generally upstream direction, opposite the normal direction of flow in the vessel.

Preferably, the vessel is a blood vessel, preferably, the aorta.

There is further provided, in accordance with a preferred embodiment of the invention, a method for augmenting blood flow into a coronary artery, comprising:

connecting a cannula, having distal and proximal ends and having an intake and a directional outlet valve, to a pump drive at the proximal end of the cannula;

inserting the cannula through the aorta, so that the distal end of the cannula is inside the left ventricle of the heart;

drawing blood from the ventricle into the cannula through the intake valve thereof; and

ejecting the blood through the outlet valve of the cannula into the aorta in a generally upstream direction, so that the blood perfuses the coronary artery.

Preferably, drawing blood and ejecting blood are performed repeatedly, in alternation.

In a preferred embodiment of the invention, drawing blood into the cannula comprises drawing blood during systole, and ejecting blood comprises ejecting blood during diastole.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic representation of a cardiac assist pump system, including a cannula having an outlet valve assembly in accordance with a preferred embodiment of the present invention, illustrating the insertion of the cannula into the heart of a subject;

Fig. 2A is a schematic, partly sectional representation of the valve assembly of Fig. 1, shown in a first, closed position, in accordance with a preferred embodiment of the present invention;

Fig. 2B is a schematic, partly sectional representation of the valve assembly of Fig. 2A, shown in a second, open position;

Fig. 2C is a schematic, partly sectional representation of the valve assembly of Fig. 2A, in an alternative configuration thereof, shown in an open position;

Fig. 2D is a schematic, partly sectional representation of another valve assembly, in accordance with a preferred embodiment of the present invention; and

Fig. 3 is a schematic, partly sectional representation of yet another valve assembly, in accordance with a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic representation of a cardiac assist pump system 18, including an intra-aortic cannula 20, which is inserted into heart 40 of a subject, in accordance with a preferred embodiment of the present invention. Cannula 20 comprises an outer sheath 22, which defines and encloses an inner lumen 24. Preferably cannula 20 has a diameter in the range of 15-30 French (5-10 mm) and is made of flexible, resilient material, for example, polyurethane reinforced with stainless steel wire, so that it can be inserted into and passed through major arteries of the human body. Cannula 20 further includes a one-way intake valve 26, preferably axially disposed, adjacent to its distal end 28, and a one-way outlet valve assembly 30, radially disposed along sheath 22 of the cannula. Cannula 20 is coupled at its proximal end to a pump 32, which functions to increase and decrease, in alternation, the pressure in lumen 24.

System 18 and pump 32 are described in greater detail in the above-mentioned PCT publication, incorporated herein by reference. It will be understood, however, that any suitable type of pump or fluid pressure source, as are known in the art, may be used in place of pump

32. Furthermore, although preferred embodiments are described herein with reference to cardiac assist pump system 18, it will be appreciated that valves in accordance with the principles of the present invention may be used in other types of medical fluid flow devices, as well.

Cannula 20 is preferably inserted percutaneously, through an incision into a peripheral artery 42, for example the femoral artery, and passed upstream through aorta 44 into left ventricle 46 of heart 40. The method of insertion is substantially similar to methods for insertion of other types of cardiac cannulae known in the art. Once cannula 20 is in place, intake valve 26 is opened, and blood flows from ventricle 46 into lumen 24. Preferably outlet valve assembly 30 is kept closed while the blood fills the lumen. Then intake valve 26 is closed and outlet valve assembly 30 is opened, so that the blood may flow out of the lumen and into aorta 44.

Figs. 2A, 2B and 2C schematically illustrate valve assembly 30, in accordance with a preferred embodiment of the present invention. Valve assembly 30 comprises a flexible, elastic outer sleeve 102, which covers and closes radial openings 104 and 105 in sheath 22 of cannula 20, which openings serve as outlet valves. Preferably, sleeve 102, is made of latex, silicone, or other biocompatible rubber, and is held in place by a squeeze ring 106. Alternatively, the sleeve may be glued or otherwise fastened in place.

In Fig. 2A, the pressure in lumen 24 has been reduced so that blood may be drawn in through intake valve 26, as described above. The elasticity of sleeve 102 causes it to adhere radially to the outer surface of cannula 20, so that outlet valve assembly 30 remains closed.

In Fig. 2B, however, the pressure of the blood inside lumen 24 has been increased. This pressure exerts an outward force on sleeve 102 through openings 104 and 105, causing the sleeve to stretch outward, and thus opening outlet valves 30. The shape of sleeve 102 as it stretches outward will generally deflect the blood ejected from lumen 24 through openings 104 in a distal direction, i.e., in a generally upstream direction, and that ejected through openings 105, in a proximal, generally downstream direction.

In Fig. 2C, valve assembly 30 is shown in an alternative configuration, in which squeeze ring 106 is repositioned axially along sheath 22 so that the ring covers openings 105. Ring 106 may be repositioned in any desired location between the distal and proximal ends of sheath 102. The location is chosen so as to direct the blood flow out of cannula 20 in a desired proportion between the distal and proximal directions. In the case shown in Fig. 2C, when

sheath 102 opens, the blood flow out of the cannula is directed in a substantially distal direction.

Fig. 2D is a schematic, partly sectional illustration showing another valve assembly 31, in accordance with another preferred embodiment of the present invention. Valve assembly 31 is substantially similar in design and operation to assembly 30 shown in Figs. 2A-2C, except that in assembly 31, proximal openings 105 are substantially smaller than distal openings 104. As a result, when valve assembly 31 opens, as shown in Fig. 2D, substantially more blood will flow out of cannula 20 in the distal direction than in the proximal direction. The sizes of the openings are preferably chosen to give a desired proportion of distal to proximal flow, in cooperation with sheath 102. This proportion may be greater than or less than one. Additionally or alternatively, the number and/or positions of openings 104 and 105 may be chosen so as to produce the desired distal/proximal proportion. Squeeze ring 106 on valve assembly 31 may also be moved to adjust the flow proportion, as described above.

Fig. 3 is a schematic, partly sectional illustration showing a directional flow valve assembly 60, which may be substituted for valve assembly 30 in cannula 20, in accordance with another preferred embodiment of the present invention. The principles of operation of valve assembly 60 are similar to those of assembly 30, described above. Assembly 60, however, includes only distal openings 104, without proximal openings 105. Alternatively or additionally, a proximal portion of sleeve 102 may be thickened and/or stiffened, relative to a more flexible distal portion, which stretches outward in response to the pressure in lumen 24, and/or the proximal portion of the sleeve may be glued in place.

When cannula 20 is inserted into aorta 44, as shown in Fig. 1, it will be observed that when valve assembly 60 opens, blood flowing out of openings 104 will be directed by sleeve 102 in a generally upstream direction, against the normal direction of blood flow. By directing the flow in this manner, the perfusion of the coronary arteries 48 may be enhanced. Preferably, pump 32 is operated in a counter-synchronized mode relative to the beating of heart 40, so that blood flows out of valve assembly 60 during diastole. Because flow and pressure in aorta 44 are normally at their lowest levels during diastole, counter-synchronous operation of the pump will allow stronger blood flow upstream from cannula 20 and into arteries 48.

It will be appreciated that the configuration of valve assembly 60 may be reversed, so that blood flows only out of openings 105, in a proximal (typically downstream) direction.

Valve assemblies 30 and 31, as described above, may also be configured and/or adjusted to direct blood flow in a similar manner.

It will further be appreciated that the preferred embodiments described above are cited by way of example, and the full scope of the invention is limited only by the claims.

CLAIMS

1. A one-way valve for use in a medical pump system, said valve comprising:

an outer sheath, defining and enclosing a lumen therein, and comprising one or more radial openings; and

an elastic outer sleeve, which adheres to an outer, radial surface of the sheath to cover the radial openings, closing the valve,

wherein in response to an increase of a fluid pressure inside the lumen, the outer sleeve stretches outward, exposing the radial openings, so that fluid flows out of the valve in a direction determined by the sleeve, and

wherein the valve is adapted to control the direction of flow.

2. A valve according to claim 1, wherein the one or more radial openings comprise at least a first opening, adjacent a proximal axial end of the sleeve, and a second opening, adjacent a distal axial end of the sleeve, such that when the sleeve stretches outward, fluid exiting the first opening flows out of the valve in the proximal direction, and fluid exiting the second opening flows out of the valve in the distal direction, in a desired proportion of proximal to distal flow.

3. A valve according to claim 2, wherein the first and second openings are of different sizes, such that the proportion of fluid flowing out of the valve in the proximal direction to that flowing out in the distal direction is determined by the relative sizes of the first and second openings.

4. A valve according to any of the preceding claims, and comprising a retaining ring, circumferentially engaging a portion of the sleeve so as to hold the sleeve in place relative to the sheath, wherein the axial position of the retaining ring along the sleeve is adjustable so as to control the flow of fluid out of the valve.

5. A one-way valve for use in a medical pump system, said valve comprising:

an outer sheath, defining and enclosing a lumen therein, and comprising one or more radial openings; and

an elastic outer sleeve, which adheres to an outer, radial surface of the sheath to cover the radial openings, closing the valve,

wherein in response to an increase of a fluid pressure inside the lumen, the outer sleeve stretches outward, exposing the radial openings, so that fluid flows out of the valve in a direction determined by the sleeve,

wherein the one or more radial openings comprise at least a first opening, adjacent a proximal axial end of the sleeve, and a second opening, adjacent a distal axial end of the sleeve, such that when the sleeve stretches outward, fluid exiting the first opening flows out of the valve in the proximal direction, and fluid exiting the second opening flows out of the valve in the distal direction, in a desired proportion of proximal to distal flow, and

wherein the first and second openings are of different sizes, such that the proportion of fluid flowing out of the valve in the proximal direction to that flowing out in the distal direction is determined by the relative sizes of the first and second openings.

6. A cannula pump comprising:

a cannula comprising having an inner lumen formed therein;

an inlet valve communicating with the lumen; and

an outlet valve in accordance with any of the preceding claims communicating with the lumen.

7. A method for controlling fluid flow out of a cannula, comprising:

opening one or more radial openings in an outer sheath of the cannula, communicating with a lumen thereof;

fitting a flexible outer sleeve over the cannula, so as to cover the one or more radial openings, wherein the sleeve stretches outward, exposing the openings, responsive to an increase in fluid pressure in the lumen;

determining a desired direction of fluid flow out of the lumen; and

fixing the sleeve to the sheath in a position such that the sleeve directs the fluid flow out of the lumen in the desired direction.

8. A method according to claim 7, wherein opening the one or more radial openings comprises opening at least two openings of different sizes, responsive to the desired direction of fluid flow.

9. A method according to claim 6 or claim 7, wherein fixing the sleeve to the sheath comprises altering the position at which the sleeve is fixed to the sheath so as to adjust the direction of fluid flow.

10. A method for injecting fluid into a vessel having a flow of liquid generally in a normal direction, comprising:

connecting a cannula, having distal and proximal ends and having an intake and a directional outlet valve, to a pump drive at the proximal end of the cannula;

inserting the distal end of the cannula into the vessel;

filling the cannula with the liquid; and

ejecting the liquid through the outlet valve of the cannula into the vessel in a generally upstream direction, opposite the direction of normal flow in the vessel.

11. A method according to claim 10 wherein the vessel is a blood vessel and the liquid is blood.

12. A method for augmenting blood flow into a coronary artery, comprising:

connecting a cannula, having distal and proximal ends and having an intake and a directional outlet valve, to a pump drive at the proximal end of the cannula;

inserting the cannula through the aorta, so that the distal end of the cannula is inside the left ventricle of the heart;

drawing blood from the ventricle into the cannula through the intake valve thereof; and

ejecting the blood through the outlet valve of the cannula into the aorta in a generally upstream direction, so that the blood perfuses the coronary artery.

13. A method according to claim 12, wherein the steps of drawing blood and ejecting blood are performed repeatedly, in alternation.

14. A method according to claim 12 or claim 13, wherein drawing blood into the cannula comprises drawing blood during systole, and wherein ejecting blood comprises ejecting blood during diastole.

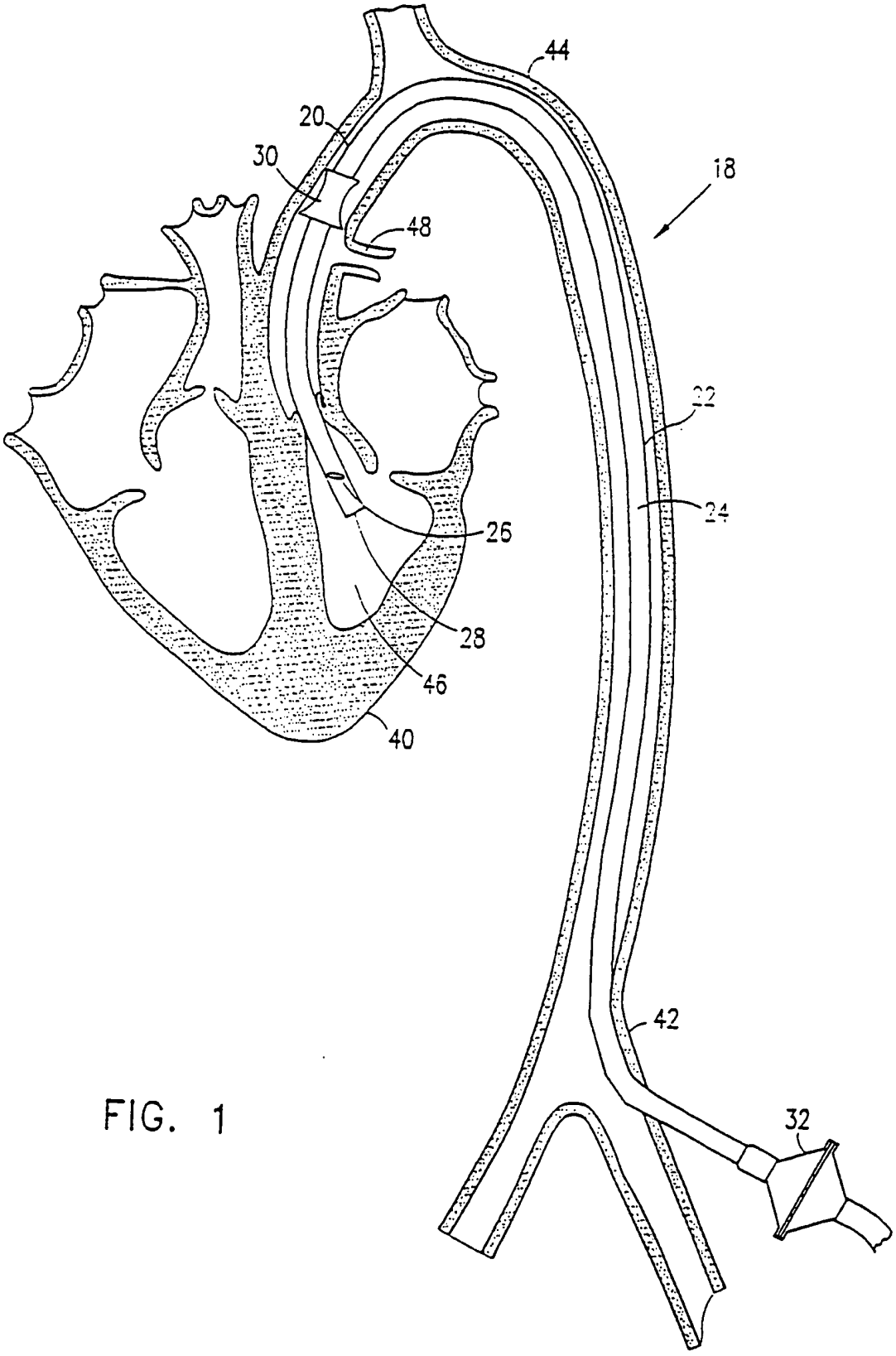


FIG. 1

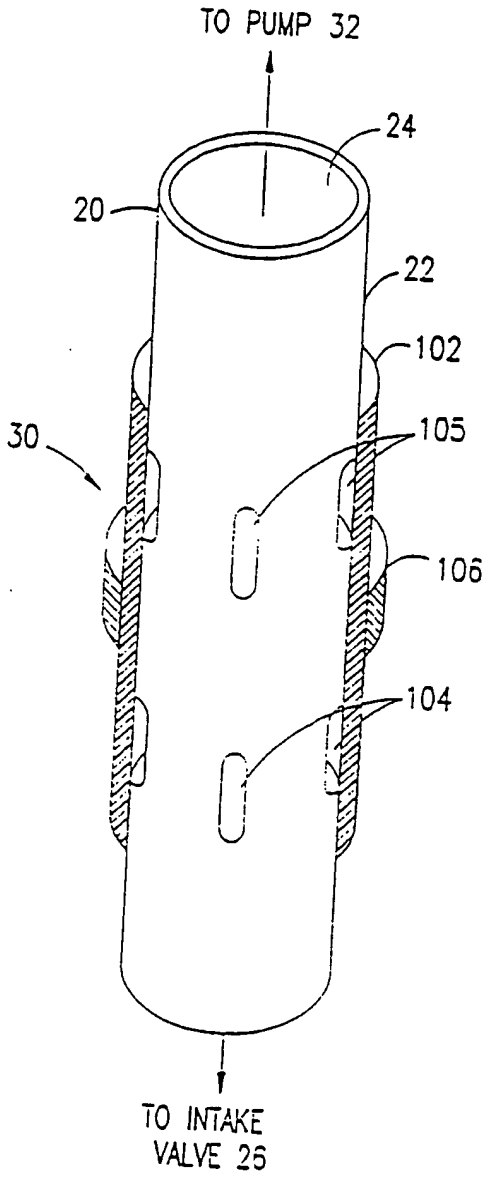


FIG. 2A

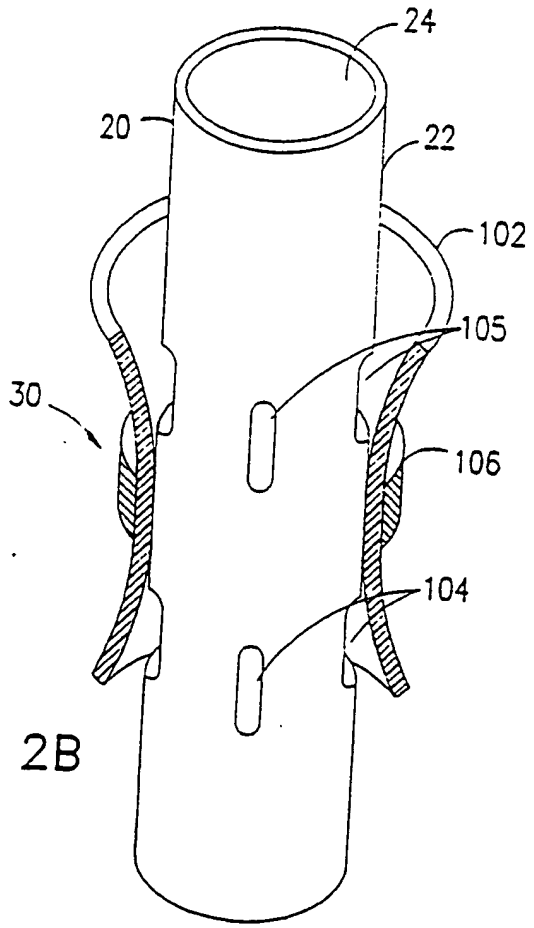


FIG. 2B

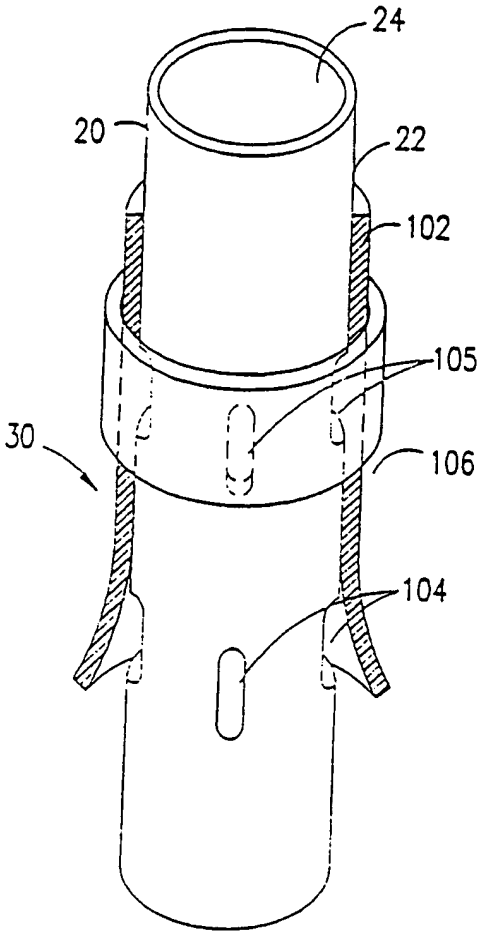


FIG. 2C

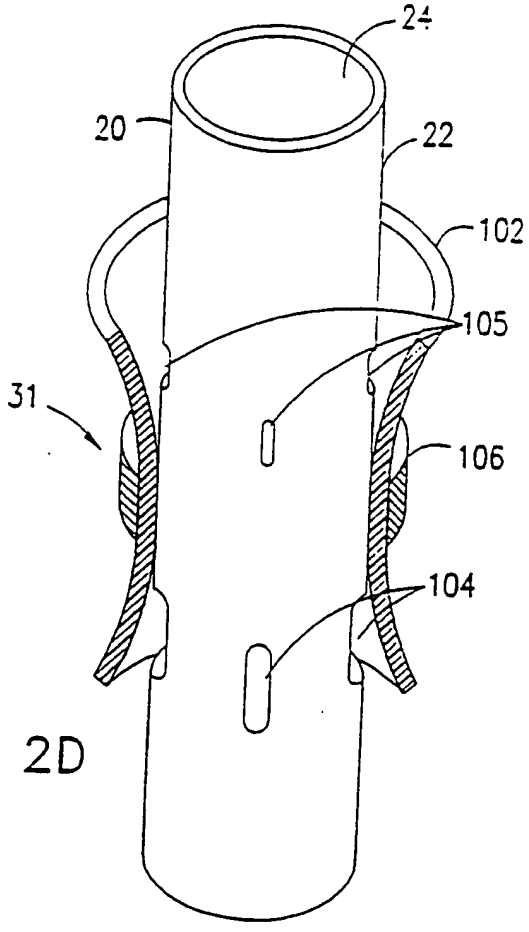
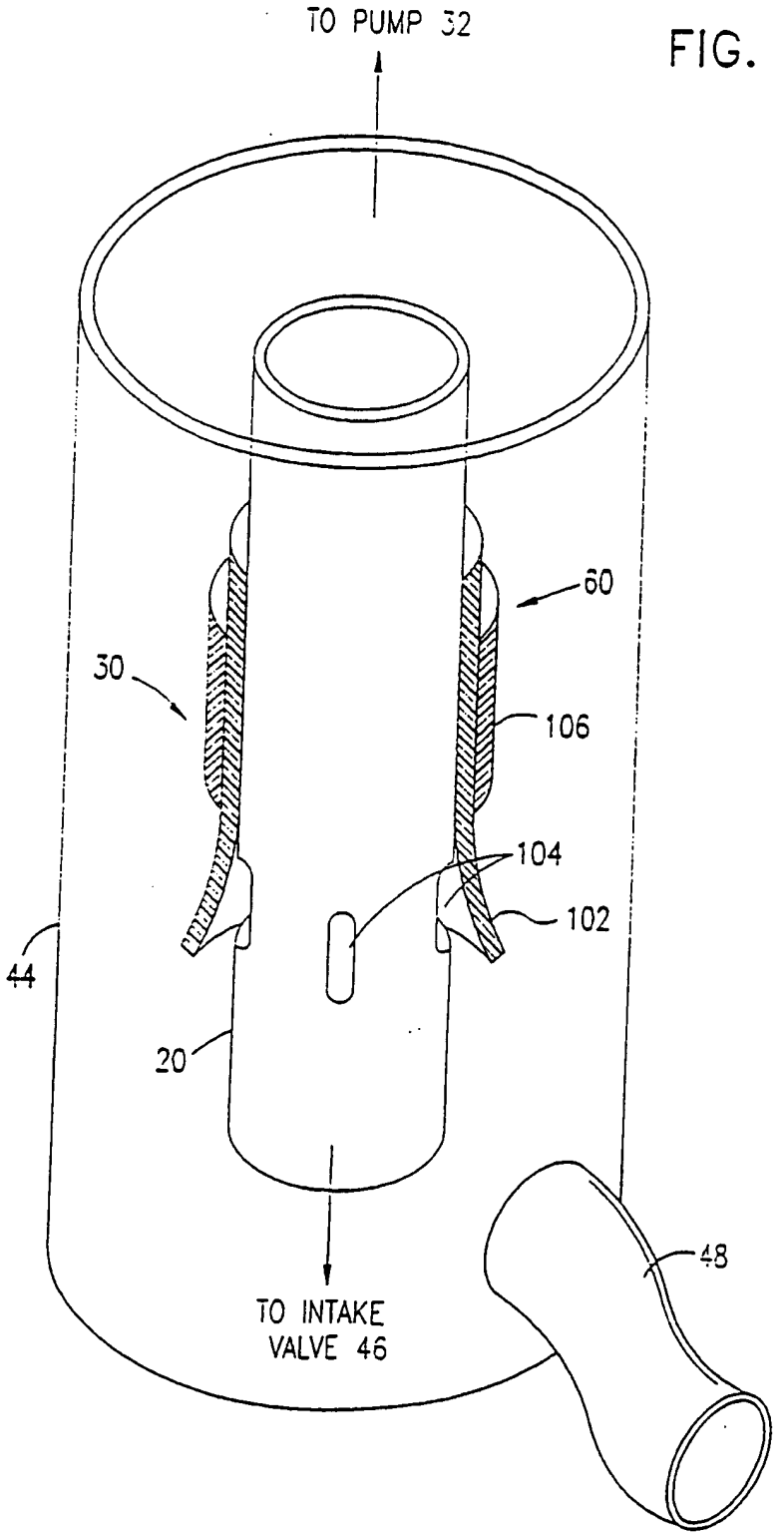


FIG. 2D

FIG. 3



INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/IL 97/00408

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00 A61M39/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M F16K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	WO 97 02850 A (RDC RAFAEL DEV CORP LIMITED ;ROTTENBERG DAN (IL); HAIMOVICH DUDU () 30 January 1997 see page 14, line 23 - line 36 ---	1-4,6
A	US 3 995 617 A (WATKINS DAVID H ET AL) 7 December 1976 cited in the application see column 3, line 60 - column 4, line 10; figures ---	1,5,7
A	US 5 520 662 A (MOSS GERALD) 28 May 1996 see abstract; figures -----	1,5,7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
24 April 1998	0 8. 05. 98
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	**Authorized officer** Villeneuve, J-M

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 97/00408

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10-14
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati. ... Application No
PCT/IL 97/00408

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9702850 A	30-01-97	AU 6317596 A	10-02-97
US 3995617 A	07-12-76	NONE	
US 5520662 A	28-05-96	NONE	